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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,089	GUY ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 9, 11 and 12, drawn to a pharmaceutical composition comprising a polynucleotide encoding OC-2 or a cell line transformed therewith, classified in class 514, subclass 44.

II. Claims 9, 11 and 12, drawn to a pharmaceutical composition comprising OC-2 having the amino acid sequence set forth in SEQ ID NO: 2, classified in class 514, subclass 2.

III. Claim 10, drawn to a pharmaceutical composition comprising a polynucleotide encoding OC-3 or a cell line transformed therewith, classified in class 514, subclass 44.

IV. Claim 10, drawn to a pharmaceutical composition comprising OC-3 having the amino acid sequence set forth in SEQ ID NO: 3, classified in class 514, subclass 2.

V. Claims 13-15, drawn to a method for prevention and/or treatment of disease comprising administering a polynucleotide encoding a peptide of the ONECUT family or a cell line transformed therewith, classified in class 514, subclass 44.

VI. Claims 13-15, drawn to a method for prevention and/or treatment of disease comprising administering a polypeptide of the ONECUT family, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The Inventions embraced by Groups I, III and V, directed to pharmaceutical compositions comprising or a method of using a nucleic acid, are distinct from the Inventions embraced by Groups II, IV and VI, directed to pharmaceutical compositions comprising or a method of using a polypeptide. Although the DNA molecule and protein are related in that the DNA encodes some embodiments of the named protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Searching the subject matter of Groups I, III and V with the subject matter of Groups II, IV and VI would impose a serious burden on the Office because the subject matter embraced by the groups is not coextensive. First, the Inventions of Groups I, III and V are separately classified from Groups II, IV and VI, which is *prima facie* evidence of the additional burden imposed by searching both inventions together. Furthermore, a search of the nucleic acid and polypeptide sequences must be performed in separate databases and a determination that the pharmaceutical composition of Groups I, III and V is patentable cannot be taken as evidence for the patentability of the pharmaceutical composition of Groups II, IV and VI, and *vice versa*. A search for the pharmaceutical composition of Groups II, IV and VI would not reasonably embrace the subject matter of Groups I, III and V because the art might disclose the polypeptide without disclosing a nucleic acid sequence encoding the polypeptide. Likewise, a search of the art for the polynucleotide of Groups I, III and V would not reasonably embrace the full scope of the subject matter of Groups II, IV and VI because the art might disclose the polypeptide sequence

determined by direct amino acid sequencing, without a disclosure of the nucleic acid sequence. Therefore, a determination that Groups I, III and V are free of the art does not adequately support patentability of the other Groups and an additional search is required to establish patentability.

The pharmaceutical compositions of Groups I and II are distinct from the pharmaceutical compositions of Groups III and IV because the pharmaceutical compositions comprise distinct active ingredients. The composition of Groups I and II comprise a nucleic acid encoding an OC-2 polypeptide or a polypeptide having the amino acid sequence set forth as SEQ ID NO: 2, respectively, and the compositions of Groups III and IV comprise a nucleic acid encoding an OC-3 polypeptide or a polypeptide having the amino acid sequence set forth as SEQ ID NO: 3. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and polypeptide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Given that the molecules that distinguish the Groups do not share a common structure, the features that define each protein and nucleic acid must be searched independently and, absent evidence to the contrary, the disclosure of any one protein or nucleic acid does not render obvious the protein or nucleic acid of the remaining Groups. Likewise, a determination that any one of the proteins or nucleic acids is free of the art does not evidence the patentability of the other proteins or nucleic acids. Therefore, because examination of each protein requires a

separate search, examination of Groups I or II together with Groups III or IV in a single application would impose a serious burden on the Office.

Finally, Inventions I and III are related to Invention V and Inventions II and IV are related to Invention VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Inventions I and III can be used in a materially different process such as in a hybridization assay and the compositions of Inventions II and IV can be used to raise an antibody or as a standard in an immunoassay. Furthermore, the nucleic acid and polypeptides used in the methods of Groups V and VI are generic to any ONECUT family member and are, therefore, not limited to using the OC-2 nucleic acid and polypeptide of Inventions I and II or the OC-3 nucleic acid and polypeptide of Inventions III and IV. Thus, the methods can be practiced using materially different products.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (see below), no such determination of patentability has been made in the instant case and the methods presently do not include all of the limitations of the product claims. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Therefore, until the product is deemed allowable, search and examination of the process

claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636